Propoxur CCA Meeting

6/16/2011

11:00am-12:00pm

- Confirm time line (from internal schedule/time table)
  - WIL Research labs have conducted carbamate CCAs in a quicker time frame. Is there a reason it will take 10 months?
- Range-finding study
  - Was an additional dose group added to the time-course phase? This could save time instead of doing the range-finding component.
  - It was previously indicated that the adults will be tested first. Is this do to study design or availability of animals? Since pups are more sensitive, it may save time to test pups first. We already have a general idea of adult inhibition from Ginger Moser's PND17 data.
- Follow-Up from 5/25 Call with Wellmark
  - Why is a cancer assessment now considered appropriate but one was not conducted for the 2010 ORE assessment?
  - The Agency initially felt that a cancer assessment may not be appropriate based on the fact that propoxur has an acute endpoint as an N-methyl carbamate. However, the Agency policy is to conduct a cancer assessment for all active ingredients that have a QSTAR value, regardless of the use pattern or endpoint. Therefore, a cancer assessment must be conducted as part of future assessments. That being said, the Agency currently believes it unlikely that a cancer assessment would significantly change the risk picture for propoxur.